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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,707	10/14/2003	Gregory Kellogg	674182-2010	4837

20999 7590 04/22/2008
FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

EXAMINER

WRIGHT, PATRICIA KATHRYN

ART UNIT	PAPER NUMBER
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1797

MAIL DATE	DELIVERY MODE
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04/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/684,707	Applicant(s) KELLOGG ET AL.	
	Examiner P. Kathryn Wright	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 16-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/25/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. This action is in response to papers filed in which claim 9 was amended. The amendments have been thoroughly reviewed and entered. Any objection/rejection not repeated herein has been withdrawn by the Office.

Claims 9-15 are under prosecution. Claims 1-8 and 16 are currently withdrawn.

Response to Amendment

2. The reply filed on January 25, 2008 is not in proper form because of the following matter(s): Applicant has made numerous amendments to the specification which cites the paragraphs as published. This not proper since all amendments should cite the page and line numbers (or paragraphs) of the specification as originally filed, not the published application. Applicant will need to resubmit the changes requested using the pages and line numbers for the specification as submitted.

Priority

3. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

4. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional

application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

5. The disclosure of the prior-filed application, i.e., US patent application No. 09/083,678 (now US Patent no. 6,063,589), fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, the prior filed application does not provide adequate support for limitation (f) in independent claim 9, namely, a read window manifold comprising a series of chambers separated by septa and arranged linearly and adjacently on the surface of the platform away from the position of the fluid connection of the manifold with the fifth microchannel.

Accordingly, **claims 9-15 are not entitled to the benefit of the prior application (US patent application No. 09/083,678) and the effective filing date of the instant invention is May 19, 1999.** If applicant disagrees, applicant is again invited to provide the area of support for claim limitations within the prior nonprovisional application.

Information Disclosure Statement

6. The supplemental information disclosure statement filed January 25, 2008 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited non-patent literature publication or that portion which caused it to be listed; and all other information

or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Applicant states in the paragraph bridging pages 14 and 15, of the above referenced Reply, that the information disclosure statement filed June 25, 2004 is in compliance with 37 CFR 1.98(a)(2) since these non-patent literature publications were previously submitted or cited by the US Patent & Trademark Office in predecessor US Patent application 09/315,114. However, the Examiner has ordered case 09/315,114 and have not found the non-patent literature publications. It is hereby requested that Applicant kindly submit these copies for Examiner's consideration.

Drawings

7. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the depression in the entry port, mixing chamber, first metering portion of the secondary metering chamber, second overflow portion of the secondary metering chamber, septum that extends from a position in the chamber farthest from the center of rotation, chamber wall, septa, read window manifold (claim 9), and heating element in thermal contact with the sacrificial valve (claim 13) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

8. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "922" has been used to designate both "secondary metering structure" and "boronate affinity matrix chamber", see page 54 of specification.

9. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

10. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: entry port depression having a volumetric capacity of about 1 to 150 microliters (note that the specification supports the *metering section* having a volumetric capacity of about 5 to 150 microliters at page 51), the first microchannel, second microchannel, third microchannel, fourth microchannel, fifth microchannel, sixth

microchannel, mixing chamber (note specification does disclose a blood lysis chamber 915), first metering portion of the secondary metering chamber, second overflow portion of the secondary metering chamber, and read window manifold.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 9-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 9 and elsewhere in the claims, “capillary microchannel”, “capillary” and “microchannel” are indefinite because applicant has not provided a clear definition of the metes and bounds of these terms. On page 8, lines 11-13, applicant states that the terms “capillary”, “microchannel”, and “microcapillary” are interchangeable. It is therefore unclear how “capillary microchannel” differs from “capillary”. Further, there is no clear definition of the dimension(s) that distinguish a microchannel from a channel. On page 14, lines 3-4, the depth of a microchannel appears to range from less than 500-800 micrometer up to 90 mm (90% of the 100 mm platform thickness). On page 15, the metering capillary has a “square cross-sectional diameter” (is that the side or diagonal of the square?) of 0.02 mm to 2.0 cm. Numerous other exemplary ranges are found throughout the text. No clear definition is provided.

Claim 9, item d) line 6, recites "a septum that extends...to a position just short of a chamber wall". The phrase "just short" is confusing and indefinite. It is not clear from the claims how "short" the septum is from the chamber wall. Clarification is requested.

Allowable Subject Matter

13. Claims 9-15 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

14. The statement of reasons for the indication of allowable subject matter can be found in the previous Official action, dated July 25, 2007.

Response to Arguments

15. Applicant's arguments filed, January 25, 2008 have been fully considered but they are not persuasive.

First, the Examiner hereby acknowledges Applicant's written request for an interview. Due to the complex nature of the invention and numerous rejections/objections that remain in the application, the Examiner believes that a written Official action on the merits is the clearest means of advancing prosecution at this time.

With respect to the earliest effective filing date of the instant invention, Applicant merely states that they are entitled to the priority date of May 22, 1998 without providing the area support for the claim limitations within the prior nonprovisional application, US patent application No. 09/083,678 (now US Patent no. 6,063,589).

Therefore, it appears the disclosure of the prior-filed application does not provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, the prior filed application does not provide adequate support for limitation (f) in independent claim 9, namely, a read window manifold comprising a series of chambers separated by septa and arranged linearly and adjacently on the surface of the platform away from the position of the fluid connection of the manifold with the fifth microchannel.

Accordingly, **claims 9-15 are not entitled to the benefit of the prior application (US patent application No. 09/083,678) and the effective filing date of the instant invention is considered May 19, 1999.** Again, if applicant disagrees, Applicant is invited to provide the area of support for claim limitations within the prior non-provisional application.

In response to the previous objection to the drawings under 37 CFR 1.83(a), Applicant has provided in the instant Reply, filed January 25, 2008, a "marked up Fig. 11A" in which Applicant states the first overflow portion is depicted as [A], first metering portion is depicted as [B], second overflow portion is depicted as [C], septum is depicted as [S], the fluid connection is depicted as [D], and the series of chambers are depicted as [V,W,X,Y,Z].

The Examiner respectfully asserts that this marked up copy in the Reply is not sufficient. The drawing in a non-provisional application must show every feature of the invention specified in the claims. Thus, Applicant should amend the appropriate figures

so that the claimed elements include reference characters with corresponding discussion in the specification, while being careful not to introduce new matter.

Furthermore, it is noted that Applicant has failed discuss where some of the claimed elements are found in the figures. Specifically, Applicant has not pointed to any element in the drawings which illustrate the depression in the entry port, chamber wall, septa, and heating element in thermal contact with the sacrificial valve.

Additionally, in the above-referenced Reply, Applicant has cited the same reference for two different claimed elements. For example, at page 15, last paragraph to page 16, last paragraph, character "915" has been used to designate both "mixing chamber" and "second metering chamber". Likewise, the reference character "922" has used to designate both the "assay chamber" and the "analyte separation chamber"

Regarding the previous objection to the specification as failing to provide proper antecedent basis for the claimed subject matter, Applicant is confused "as claims as filed are part of the disclosure and therefor, if an application as originally filed contains a claim disclosing material not disclosed in the remainder of the specification."

The Examiner is not clear what is confusing Applicant. The rules of the PTO require that application claims must "conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description." See 37 CFR 1.75(d)(1). Accordingly, Applicant should amend the specification to include the claimed elements not found in originally filed application, namely, an entry port

depression having a volumetric capacity of about 1 to 150 microliters (note that the specification supports the *metering section* having a volumetric capacity of about 5 to 150 microliters at page 51), the first microchannel, second microchannel, third microchannel, fourth microchannel, fifth microchannel, sixth microchannel, mixing chamber (note specification does disclose a blood lysis chamber 915), first metering portion of the secondary metering chamber, second overflow portion of the secondary metering chamber, and a read window manifold.

In response to the rejection to claims 9-15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, Applicant argues the terms “capillary microchannel”, “capillary” and “microchannel” are exemplified in the specification as originally filed.

The Examiner respectfully does not agree. As stated previously, the claims recite, a “capillary microchannel”, “capillary” and “microchannel”. These terms are indefinite because applicant has not provided a clear definition of the metes and bounds of these terms. On page 8, lines 11-13, applicant states that the terms “capillary”, “microchannel” and “microcapillary” are interchangeable. It is therefore unclear how “capillary microchannel” differs from “capillary”. Further, there is no clear definition of the dimension(s) that distinguish a microchannel from a channel. On page 14, lines 3-4, the depth of a microchannel appears to range from less than 500-800 micrometer up to 90 mm (90% of the 100 mm platform thickness). On page 15, the metering capillary has a “square cross-sectional diameter” (is that the side or diagonal of the square?) of

0.02 mm to 2.0 cm. Numerous other exemplary ranges are found throughout the text.

No clear definition is provided.

With respect to the recitation in claim 9, that “a septum that extends...to a position just short of a chamber wall”, Applicant argues the phrase "just short" is found throughout the specification, see page paragraphs 15, 172, 184, 199, 262 and 275 of the corresponding published application.

The Examiner respectfully asserts that this is not sufficient. While the phrase “just short” may be used throughout the specification, however it is not defined. Thus, it remains unclear how "short" the septum is from the chamber wall, that is, what are the dimensions.

Conclusion

16. Claims 9-15 are currently rejected.

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is 571-272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

April 21, 2008
pkw

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797